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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| | EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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| Office Action Summary | Application No. | Applicant(s) |
| | 09/485,421 | MAHALINGAM ET AL. |
| | Examiner Bharati R. Dhruba | Art Unit 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

| | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I claim 1-11, drawn to a conjugated composition comprising Vpr linked to nucleic acid and a method of delivering the nucleic acid to the nucleus of a cell using the conjugated compound.

Group II claims 12-16,25-27, drawn to a Vpr protein as a therapeutic compound.

Group III, claims 13-14, 17-20, drawn to Vpr conjugated to nucleic acid as a therapeutic agent.

Group IV claims 21-24, drawn to a method of identifying compound that inhibits Vpr protein binding to p6 protein.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The general inventive concept for group I is Vpr linked to nucleic acid. The general inventive concept for group II is Vpr protein as a therapeutic agent. Group I composition differs from group II protein by biochemical and biophysical properties, furthermore group II protein can be used for production of antibodies or in as a therapeutic agent. The general inventive concept of group III is nucleic acid encoding Vpr as a therapeutic agent. The group I composition has protein linked to a therapeutic DNA which has different structure and sequence from the group III nucleic acid. Group IV inventive concept is an assay to identify compounds that inhibits Vpr-p6 binding. The method of group IV does not use the composition of group I.

The general inventive concept for group II is Vpr protein as a therapeutic agent. The general inventive concept of group III is nucleic acid encoding Vpr as a therapeutic agent. The group II protein and group III nucleic acid has different biochemical and biophysical properties. Furthermore group III nucleic acid can be used as a probe or for cell transformation. Group IV inventive concept is an assay to identify compounds that inhibits Vpr-p6 binding. The method of treatment for therapy in group IV and method for identifying an inhibitor have different ingredients, method steps and endpoints.

The general inventive concept of group III is nucleic acid encoding Vpr as a therapeutic agent. Group IV inventive concept is an assay to identify compounds that inhibits Vpr-p6 binding.

A telephone call was made to Mr. Mark DeLuca on June 5th '00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bharati R. Dhruva whose telephone number is (703) 308-1157. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached on (703)-308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are for regular communications and (703) 305-3014 for After Final communications.

Question of formal matters can be directed to the patent analyst Phillip William , whose phone number is (703) 305-3482.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0196.

BRD

June 14, 2001

R. A. Schwartzman
ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER
